

Application, No. 09/980,586
Amendment dated November 30, 2003
Reply to Restriction Requirement mailed May 29, 2003

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-97: (Canceled)

98. (New) A method for prophylactically or therapeutically treating Alzheimer's disease in a mammal comprising administering to the mammal a sufficient amount of a sterile aqueous suspension comprising at least 0.05 mg/ml of A β peptide in a regime effective to induce an immunogenic response comprising antibodies to the A β peptide, wherein the aqueous suspension is maintained at a physiologically acceptable pH and the suspension is prepared by adjusting the pH of an aqueous solution sufficient to solubilize said A β peptide; filtering the resulting suspension through a hydrophilic filter; and adjusting to a physiologically acceptable pH to form the aqueous suspension, and thereby prophylactically or therapeutically treat Alzheimer's disease in the mammal.

99. (New) The method of claim 98, wherein the resulting suspension is maintained at a physiologically acceptable pH by use of about an effective amount of a pharmaceutically acceptable buffer.

100. (New) The method of claim 98, wherein the A β peptide is a long form of A β peptide.

101. (New) The method of claim 100, wherein said A β peptide is A β 42.

102. (New) The method of claim 98, wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

103. (New) The method of claim 102, wherein the physiologically acceptable pH is maintained at a pH is about 5.5 to about 6.5.

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104. (New) The method of claim 99, wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.

105. (New) The method of claim 104, wherein the pharmaceutically acceptable buffer is an amino acid, salt and derivative thereof.

106. (New) The method of claim 105, wherein the pharmaceutically acceptable buffer is an amino acids, salts and derivatives thereof glycine (sodium glycinate) or arginine (arginine hydrochloride).

107. (New) The method of claim 104, wherein the pharmaceutically acceptable buffer is acetate (sodium acetate), or citrate (sodium citrate).

108. (New) The method of claim 98, wherein the sterile aqueous suspension has an A₆₄₂ concentration of 0.1 to 0.8 mg/ml in a pharmaceutically effective buffer of 10 mM glycine, and the physiologically acceptable pH is maintained at a pH of about 5.5 to about 6.5.

109. (New) The method of claim 98, wherein the sterile aqueous suspension further comprises sucrose.

110. (New) The method of claim 109, wherein the amount of sucrose is sufficient to provide a 5% (w/v) sucrose suspension.

111. (New) The method of claim 98, wherein the sterile aqueous suspension further comprises polysorbate 80.

112. (New) The method of claim 98, wherein the sterile aqueous suspension is free of polysorbate 80.

113. (New) The method of claim 98, wherein the sterile aqueous suspension further comprises a pharmaceutically acceptable adjuvant.

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114. (New) The method of claim 113, wherein the adjuvant is selected from the group consisting of incomplete Freund's adjuvant; MPL; QS-21 and alum.

115. (New) The method of claim 114, wherein the adjuvant is QS-21.

116. (New) The method of claim 115, wherein the sterile aqueous suspension is a visually clear suspension having an A₆₄₂ concentration of at least 0.1, an effective amount of QS-21 and the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

117. (New) The method of claim 115, wherein the sterile aqueous suspension is a visually clear suspension having an A₆₄₂ concentration of 0.1 to 1.0 mg/ml in a pharmaceutically effective buffer of 10mM glycine, the adjuvant is at least 0.1 mg/ml of QS21, and the physiologically acceptable pH is maintained at a pH of about 6.

118. (New) The method of claim 101, wherein the sterile aqueous suspension is a visually clear suspension further comprising an effective amount of DPPC (dipalmitoyl phosphatidyl chloride) and the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

119. (New) The method of claim 118, wherein the sterile aqueous suspension has an A₆₄₂ concentration of at least 0.1 mg/ml and the physiologically acceptable pH is maintained at a pH of about 6.

120. (New) The method of claim 98, wherein the method further comprises administering a pharmaceutically acceptable adjuvant separately or admixed in within the said sterile composition.

121. (New) The method of claim 113, wherein the sterile aqueous suspension is administered parentally.

122. (New) The method of claim 98, wherein the sterile aqueous suspension is administered parentally.